

### REMARKS

Claims 1, 5-7, 9, 25-30 and 69-76 are pending. The allowed claims are 26, 28, 30 and 70 and all other pending claims stand rejected. The Examiner has noted that the Declaration and Oath of Mark Keating is defective and Applicants are submitting this day under separate cover a new Declaration and Oath executed by inventor Mark Keating. Also submitted this day under separate cover are formal drawings for this application. The Examiner has also objected to claims 1, 7, 71 and 74 and applicants have amended the relevant claims.

#### *35 U.S.C. § 112, first paragraph rejections*

Claim 9 remains rejected under 35 U.S.C. § 112, first paragraph for lack of a written description. The Examiner has rejected this claim because the disclosure does not provide sufficient description of polymorphic sites other than the ones listed at pages 72-73. Claim 9 has been amended to recite a primer suitable for performing a single base extension across a polymorphic site selected from the group consisting of nucleotide numbers 95, 98, 234 and 243, said sites being disclosed at page 72-73 of the specification.

In view of the amendments to the claims and above arguments, it is believed the claims are in condition for allowance and Applicants request that the rejection of claim 9 under 35 U.S.C. § 112, first paragraph for lack of written description be withdrawn.

Claims 5-7, 9 and new claims 72 and 73 were rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner has acknowledged that the specification is enabling for an isolated nucleic acid coding for SEQ ID NO: 2 or its complement and primers for performing single base extensions across the polymorphic sites described above. The essence of these rejections is that there are no suggestions as to what the target sites for said probes or primers in SEQ ID NO:2 are or what modification can be made while retaining the functional limitation of hybridizing under stringent hybridization conditions. The relevant claims have been amended or canceled to recite probes or primers that will hybridize under stringent conditions to specific alleles taught in the specification. Given the state of knowledge possessed by a person of ordinary skill in the art at the time of the application, it would not require undue

experimentation to construct probes or primers which specifically recognized the disclosed allelic variants.

In view of the amendments to the claims and above arguments, it is believed the claims are in condition for allowance and Applicants request that the rejection of claims 5-7, 9 and 72-73 under 35 U.S.C. § 112, first paragraph for lack of enablement be withdrawn.

Claims 1-9 and 24-30 were rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Examiner is of the opinion that the previously cited references of Kurz and Straussberg, and newly cited references Feder and/or Murai all contain at least some sequences complementary to SEQ ID NO:2. The Examiner is of the opinion that the cited sequences will bind to the claimed sequence under stringent hybridization conditions and will also be considered "complementary" thereto. The Examiner is therefore of the opinion that it would require undue experimentation to identify the nucleic acids encompassed by the claims. Claim 1 has been amended to recite isolated nucleic acids that contain the full complement of the nucleic acid coding for the polypeptide of SEQ ID NO:2. Claim 5 has been amended to recite allele specific probes or primers that hybridize to a nucleic acid for the polypeptide of SEQ ID NO:2 at the specific polymorphic sites defined in the specification.

In view of the amendments to the claims and above arguments, it is believed the claims are in condition for allowance and Applicants request that the rejection of claims 1-9 and 24-30 under 35 U.S.C. § 112, first paragraph for lack of enablement be withdrawn.

*35 U.S.C. § 112, second paragraph rejections*

Claim 25 and 71 were rejected under 35 U.S.C. § 112 second paragraph as indefinite. Claim 25 has been amended to recite an *in vitro* cell transfected with the DNA of claim 1. In view of the amendments to the claims and above arguments, it is believed that these claims satisfy the applicable provisions of the patent statutes and it is requested that this ground of rejection be withdrawn.

*35 U.S.C. § 102 rejections*

Claims 1, 5-7, 25, 69 and 71-75 were rejected under 35 U.S.C. § 102(b) as anticipated by Kurtz. The Examiner is of the opinion that regions of the sequence disclosed in Kurtz will be complementary to SEQ ID NO:2 along some portion, even if it is one base pair in length.

Applicants have amended claim 1 to recite a nucleic acid having the amino acid sequence set forth in SEQ ID NO:2 or an isolated nucleic acid coding for the full complement of said nucleic acid. Claim 5 has been amended to recite probes or primers that hybridize with the polymorphic sequences disclosed herein, which are not present in the cited prior art.

In view of the amendments to the claims and above arguments, it is believed that these claims satisfy the applicable provisions of the patent statutes and it is requested that this ground of rejection be withdrawn.

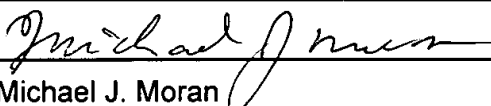
Claims 1, 5-7, 25, 27, 29, 69 and 71-76 were rejected under 35 U.S.C. § 102(a) as anticipated by Strausberg. The claims have been amended and Applicants have also submitted a Declaration under 37 C.F.R. 1.131 signed by all named inventors indicating that the present sequences were invented by the Applicants prior to the invention date cited for Strausberg.

In view of the amendments to the claims, Rule 1.131 Declarations and above arguments, it is believed that these claims satisfy the applicable provisions of the patent statutes and it is requested that this ground of rejection be withdrawn.

*Amendment of Allowed claims*

The Examiner has indicated that claim 70 is allowable. Claim 70 has been amended to recite an isolated "nucleic acid" in place of an isolated "DNA" coding for a mutated MiRP1 polypeptide. It is believed that this amendment does not constitute new matter and its entry is requested.

In view of the above arguments and amendments to the claims, it is urged that all of the presently pending claims satisfy the provisions of the patent statutes. Reconsideration of this application and early notice of allowance are requested. The Examiner is invited to telephone the undersigned to expedite allowance of this application.

RESPECTFULLY SUBMITTED,					
					
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**Attachments:** Marked-Up Copy of Claims showing Amendments

**Marked up copy of amended claims with additions underlined and deletions in brackets.**

1.(Twice amended) An isolated nucleic acid coding for a human MiRP1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO:2 or an isolated nucleic acid [complimentary to] which is the full complement of said nucleic acid coding for a human MiRP1 polypeptide.

5. (Twice amended) An allele specific probe or primer which hybridizes to a nucleic acid encoding a polypeptide of SEQ ID NO:2 under stringent hybridization conditions, wherein said stringent hybridization conditions comprise a temperature of at least 45°C with a salt concentration less than 200 mM and the allele-specific probe or primer hybridizes to said nucleic acid at a polymorphic site selected from the polymorphic sites consisting of nucleotide numbers 95, 98, 234 and 243 of SEQ ID NO:1

7. (Twice amended) The probe or primer of claim 6 that comprises at least ten contiguous bases of nucleic acid encoding a polypeptide of SEQ ID NO:2 or at least ten contiguous bases of nucleic acid [encoding a sequence complimentary] which is the full complement of said contiguous bases of nucleic acid encoding a polypeptide of SEQ ID NO:2.

9. (Twice amended) A primer suitable for performing a single base extension reaction across a polymorphic site selected from the polymorphic sites consisting of nucleotide numbers 95, 98, 234 or 243 of SEQ ID NO:1, which primer hybridizes to a subsequence of SEQ ID NO:1 or the complement thereof, which subsequence terminates at a base immediately adjacent to and 5' from a base selected from the group consisting of nucleotide numbers 95, 98, 234 or 243.

25. (Twice amended) An *in vitro* cell transfected [*in vivo*] with the DNA of claim 1.

70. (Amended) An isolated [DNA] nucleic acid coding for a mutated form of the MiRP1 polypeptide sequence set forth in SEQ ID NO:2, wherein said mutated form comprises a

mutation selected from the group consisting of: an Ala at amino acid 8; a Glu at amino acid 9; a Thr at amino acid 54; and a Thr at amino acid 57.

71. (Amended) An isolated nucleic acid coding for (a) a mutated form of the nucleotide sequence set forth in SEQ ID NO:1 or (b) a nucleic acid [complimentary to] which is the full complement of said nucleotide sequence, wherein said mutated form [copies] comprises nucleotides 74-442 of SEQ ID NO:1 having a nucleotide change selected from the group consisting of: an A to a G at nucleotide 95; a C to a G at nucleotide 98; a T to a C at nucleotide 234; and a T to a C at nucleotide 243.

72. (Amended) An allele specific probe or primer which hybridizes to the DNA of claim 70 under stringent hybridization conditions, wherein said stringent hybridization conditions comprise a temperature of at least 45°C with a salt concentration less than 200 mM, wherein the allele specific probe or primer hybridizes to said DNA at a polymorphic site selected from the group consisting of nucleotide numbers 95, 98, 234 and 243.

74. An isolated nucleic acid which comprises the nucleotide sequence set forth in SEQ ID NO:1 or a nucleic acid [complimentary] which is a sequence fully complementary to said sequence.